KENNY C. GUINN
Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

DRUG USE REVIEW (DUR) BOARD

Location of Meeting
Legislative Building
401 South Carson Street – Room 2135
Carson City, NV

Meeting Minutes
June 30, 2005
Time: 1:00 p.m.

Committee Members Present:
David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.

Marjorie Uhalde, MD (called in 1:00 p.m.)
Steven Parker, MD (called in 1:30 p.m.)

Others Present:
Charles Duarte DHCFP, Mary Wherry DHCFP, Coleen Lawrence DHCFP, Vickie Langdon DHCFP, Darrell Faircloth AGO, Jeff Monaghan FHSC, Shirley Hunting FHSC, Dawn Daly FHSC, Katie Johnson FHSC, Bert Jones GSK, Richard Harris MD, Joe Duarte Cephalon, Tim Hambachor Abbott Diabetes Care, Paul Pereira TAP, Laurie Squartsoff Eli Lilly, Alan Sloan Purdue, Susan Fisher Astra Zeneca, Tracey Meeks Amylin, Katherine Hollingsworth Takeda, Garrett Hall Electronic Healthcare Services, Chris Shea Diversified Medication Consulting

I. Call to Order and Roll Call

David England, Chairman, called the meeting to order at 1:06 p.m.

II. *Discussion and Approval of March 31, 2005 Minutes

MOTION: Keith Macdonald motioned to accept the minutes as written.
SECOND: Marjorie Uhalde
VOTES: Unanimous
MOTION CARRIED.

III. Presentation by DHCFP Regarding Recent CMS Directives Affecting Payment of Erectile Dysfunction Drugs for Registered Sex Offenders

Charles Duarte, Administrator, DHCFP, provided the Committee with information on Medicaid's coverage of erectile dysfunction (ED) drugs for registered sex offenders. On May 22nd, the New York Times released a report by the New York controller's office that an audit of their Medicaid Program indicated that approximately 200 high risk sex offenders had been issued prescriptions for ED drugs through the Medicaid Program. On May 23, Dennis Smith, Director, Center for Medicaid and State Operations with CMS, issued a letter to states which provided guidance with respect to the coverage of ED drugs.

Mr. Duarte stated that a number of states have taken a variety of actions, some prior to this announcement by the New York controller's office. CMS has also taken steps to curtail or control the use of this class of drug not specific to this category of recipient but overall. It was noted that there are benefits for some individuals with a diagnosis of pulmonary hypertension as well as paraplegics and quadriplegics who could be affected if they did not have access to these types of drugs.

Public records on high risk sexual offenders (Level 3) are available through the Nevada's Department of Public Safety. DHCFP and FHSC conducted a review of prescriptions for these medications screening the recipients against the public registry and found three recipients who had received ED medications in the fee-for-service program in Nevada. As a result of the guidance from CMS, authorization for ED drugs for these three recipients has been discontinued.

DHCFP continues to manually screen the public registry when requests for ED medications are received by FHSC for male recipients. Authorization will be denied if the recipient is on the registry of level 3 sex offenders.

Mary Wherry, Deputy Administrator, DHCFP, stated that currently, Nevada Medicaid has 286 recipients receiving ED medications ranging in age from late teens to the late 80's. In the past twelve months, 1,554 prescriptions for ED drugs have been filled.

Ms. Wherry brought the Board up to date on what is occurring at the federal level referring to House Bill 712 (heard on 6/24/05 and passed with a 2 to 1 margin) and Senate Bill 1113. She stated, if passed, these bills would amend the Medicare Modernization Act and disqualify or ban any federal dollars to the Medicare and Medicaid programs from paying for erectile dysfunction drugs. The actual language states that no federal funds may be expended for the payment or reimbursement of a drug that is prescribed for the treatment of sexual or erectile dysfunction. This would ban Medicare and Medicaid for drugs prescribed for the treatment of impotence. Currently, Medicaid spends approximately $15 million a year nationwide on erectile dysfunction drugs and the congressional budget office projects that under Medicare Part D, in the next ten years, government will be

spending about 2 billion dollars. Barring any federal legislation that would mandate otherwise, she offered the following options:

1) Maintain the current policy and be exposed for potential sanctions. The state Medicaid director's letter closed with a statement that sanctions could be applied to states. The form or amount of sanctions was not stated.

2) Maintain the current policy and add an edit in the claims payment system that would prohibit payment for claims for convicted sexual offenders. She stated that it is not known what decision would be made should a recipient identified as a sexual offender need an ED drug for pulmonary hypertension or other approved diagnosis other than erectile dysfunction.

3) Eliminate the provision for erectile dysfunction drugs for all Medicaid recipients except for those qualifying with certain conditions such as pulmonary hypertension, quadriplegia, or paraplegia.

4) Eliminate the erectile dysfunction drugs entirely and only allow it on exception for early periodic screening, diagnosis and treatment (EPSDT) situations through a fair hearing process.

Dave England asked if there are statistics on how many of our Medicaid patients have been or are being treated for pulmonary hypertension.

Ms. Wherry stated that two people, one in the teens and one in the 80's, one being female, are currently being treated for pulmonary hypertension and added that it is not mandatory data collection for the Point of Sale system to capture diagnosis. It would not be easy or a one-hundred percent conclusive way to run a report from that data or matching it to MMIS to say what the diagnosis may be. A claim could be submitted based on that treatment episode which may not necessarily capture other diagnoses which may be out there.

Dave England asked if there could be sex offenders on the medication who have not made the list which is checked against. Ms. Wherry stated that is correct.

Dave England asked if there is some reason from keeping us from seeing anyone who has had any conviction or can we only look at those who have had multiple convictions or on the high risk list.

Mr. Duarte responded that Nevada law requires that the publicly available list only include the level 3 offenders and some of the high risk level 2 offenders. That law was recently changed during the last legislative session to allow the public access to level 2 offenders but that leaves level 1 and level 0. That data is available through FBI files which can potentially be accessed. DHCFP is currently working with the Nevada State Welfare Division and the Nevada Department of Public Safety to gain access but there are confidentiality rules that are precluding that.

Mr. England expressed concern that eventually these drugs will not be allowed for anyone because of limited access to the information verifying who has or has not had a sexual offense.

Mr. Duarte stated that his office is working with the Governor's office and the respective offices involved with these records to gain access to the FBI files which will include, on a national level, all convicted sex offenders.

Keith Macdonald asked what the dose level is for pulmonary hypertension as the current policy has a limitation of eight tablets per month.

Jeff Monaghan stated that the standard dose for pulmonary hypertension is 20mg given three times per day versus the average for impotence of 50mg given as a single dose. Based on utilization of the drug and on the dose, there appears to be 2 or 3 patients currently being treated for pulmonary hypertension.

Dave England requested Ms. Wherry give a brief overview for Dr. Parker who joined the meeting while her presentation was in progress.

Dr. Parker felt the practical approach would be to monitor the list and deny the request if the recipient is on the registry.

Darrell Faircloth asked if the criteria found under the tab, Erectile Dysfunction Discussion, labeled Appendix A, is the current limitation or the proposed limitation.

Coleen Lawrence stated that is the current policy. Currently, only level 3 and some extreme level 2 offenders are available on the Public Safety web site. For legal reasons, if the policy changes, the PA form may need to be modified to include a check box asking if the recipient is a sexual offender.

Dave England asked about individuals that are known level 3 offenders which have been rehabilitated.

Mr. Faircloth stated that there is an appeal process which they can go through to try and show why the limitation should not apply. There are a large number of unanswerable questions within this particular problem ranging from the fact that many sexual offenders are not properly registered or traverse in and out of the state and don't appear on the lists but may reside here and may be Medicaid recipients. The question that someone may be rehabilitated or that some of these convictions may not be relevant to a person's current character, that's a question left to an appeals process. For the most part, someone who reaches a Tier 3 status, is a lifetime offender and unlikely to change.

Keith Macdonald asked when a drug would be a psychotherapeutic necessity for the patient to maintain a family or a relationship and should that be a qualification for limitations. Referring to subsection 5 of the criteria, does it suggest that

without the drug, they would have a failed relationship, marriage or some other circumstance?

Dr. Parker asked if Mr. Macdonald is talking about the sexual offender or anyone in general.

Mr. Macdonald replied people that would be authorized the medication and added that his recommendation would be to prohibit all sexual offenders from obtaining the medication.

Ms. Wherry pointed out that the recommendation, at this point, is to continue to monitor and not approve authorization for sexual offenders and added that Mr. Macdonald's question is beyond that. At what point or how would it be determined whether the drug is necessary for a quality of life issue that may have some psychological consequences to it and should that be an additional criteria. She stated that her response to that would be to leave it up to the physicians to determine medical necessity.

IV. *Action by Board to Revise Current Prior Authorization Criteria for Erectile Dysfunction Drugs

Mr. England entertained a motion to accept, as discussed today, continuing the screening criteria to the best of our ability with the information available and continue to review as more information becomes available; to re-review or add additional criteria if a valid quality of life measure can be determined. Dr. Uhalde so moved with a second by Dr. Parker. There was no vote.

Darrell Faircloth requested a clarification of the motion. He stated that the guidelines presented are the current limitations in effect for erectile dysfunction medications. What the Committee contemplated was that additional restrictions would be placed on the medications and that a clear record of those restrictions needs to be stated particularly with regard to sexual offenders.

Mr. England suggested adding a section "c" and Ms. Lawrence recommended adding language to the effect that the Division and Contractor will screen to the best of their ability the sexual offenders registries. If a recipient is found to be on the registry, the medication will be denied.

MOTION: Keith Madonald motioned to add an item "c" to the current criteria stating that the medication will be denied if the recipient is on a current available sexual offenders' registry or list.
SECOND: Marjorie Uhalde
VOTES: Unanimous
MOTION CARRIED.

V. *Presentation by First Health Services and Action by Board on Suggested Changes to Clinical Prior Authorization Criteria for the Following Drugs and/or Drug Classes

At the March meeting, the DUR Board requested a review of current prior authorization (PA) criteria for agents containing black box warnings. Jeff Monaghan stated that the PA criteria for those agents have been modified to reflect the black box warnings and presented the proposed changes which incorporate the warnings (attached - black box warnings are bolded and underlined; notations in bold are included for statements/paragraphs removed/revised). Mr. Monaghan reviewed the main changes.

A. Cox II Inhibitors

-Criteria 2 revised (authorization will not be given for the diagnosis of gastritis only)
-Criteria 5 and 6 added (documented history of cardiac events)
-Criteria 7 added (alternative treatment options considered)
-Time Period (based on diagnosis not age)

Dave England asked if the changes are based on package insert and current literature.

Mr. Monaghan stated that they are. He added that on June 15, the FDA released, on their Med Watch List Serve, more information requesting manufacturers of all NSAID's, for both prescription and OTC products, make labeling changes to include a boxed warning highlighting the potential for increased risk of cardiac events and GI bleeding. The FDA also will require that the "Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)" (attached) be given to patients who receive any NSAID.

Dr. Parker recommended combining criteria 5 and 6 as both address cardiac events.

MOTION: Dr. Parker motioned to accept the criteria as presented combining criteria 5 and 6.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED.

B. Fentanyl Transdermal Patches

-Added contraindications (because serious or life-threatening hypoventilization could occur)
-Criteria 1 added (patient cannot be managed by lesser means)
-Criteria 2 added (patient requires continuous opioid administration)
-Criteria 8 added (patient becomes Medicaid-eligible and pain is being managed effectively with transdermal [existing criteria] 6 and 7 apply)

Mr. Monaghan referred to the existing criteria 3, 4, 5 and stated that the criteria currently requires patients to fail oral therapy before transdermal therapy is approved. The result was an increase in oral therapy particularly Oxycontin use. He added that it is now financially to the State's advantage to allow the physician the choice of prescribing oral or transdermal. An edit is currently in place which does not allow both an oral long-acting and transdermal long-acting. He recommended eliminating the existing criteria 3, 4, and 5.

Dave England stated that he does not want to restrict the physician's ability to treat their patient's pain but he also would like a "firewall" to hinder potential abuse by the physician or patient. If this accomplishes that, he is favorable to the change.

Dr. Parker said that the existing criteria 3, 4 and 5 are addressed in criteria 1. He recommended combining those criteria into number 1. He added that he takes exception with the FDA's wording in the black box warning that the patch is not indicated for post-operative pain. There are situations when a patient can have post-operative pain for 1-2 weeks based on trauma or other issues or have ongoing surgeries. It may be more appropriate to manage those patients with a patch rather than oral therapy.

Mr. England responded that if there is a patient in that situation, because there is literature which supports use for that purpose, a prior authorization can be given.

Dr. Uhalde referred to criteria 6 questioning why only terminally ill and hospice patients can be dosed every two days because a fast metabolizer may not be terminal, but may require two day dosing.

Dr. Parker stated that he agreed with what Dr. Uhalde is saying. He asked if there is a way to prove that someone is a fast metabolizer as Duragesic patches are one of the most highly abused narcotics.

Mr. England suggested including verbiage such as dosing interval one patch every three days, but may be dosed every two days if documented pain relief not achieved, requiring the patient and physician to keep a log that could be provided to the Clinical Call Center.

Mr. Monaghan will modify the criteria to include language as recommended.

MOTION: **Keith Macdonald motioned to accept criteria 1, 2, 6, 7, 8, and eliminate criteria 3, 4, and 5.**
SECOND: **Dr. Parker**
VOTES: **Unanimous**
MOTION CARRIED

C. Anti-fungal Onychomycosis Agents

-Criteria 1 added (itraconazole – do not authorize if recipient has evidence of ventricular dysfunction)
-Criteria 2 added (terbinafine – do not authorize if recipient has pre-existing liver disease)

MOTION: Dr. Parker motioned to accept the criteria as presented.
SECOND: Dr. Uhalde
VOTES: Unanimous
MOTION CARRIED.

D. Ramipril (Altace)

-Added: do not authorize if the patient is pregnant

Dave England asked if this is for Altace or all of the ace inhibitors. Dr. Uhalde stated that it is for all ace inhibitors.

MOTION: Keith Macdonald motioned to accept the criteria as presented.
SECOND: Dr. Parker
VOTES: Unanimous
MOTION CARRIED

E. Ketoralac (Toradol) tablets

-Added: indicated for short-term (up to 5 days) management of moderately severe acute pain that requires analgesia at the opioid level…not indicated for minor or chronic pain
-Criteria 1 added (oral treatment indicated only as continuation therapy to IV/IM therapy)
-Criteria 2 added (oral treatment is not to exceed 5 days)
-PA not required for 20 or less tablets per month; prescriptions for a quantity of more than 20 tablets in the past six months requires a PA

Mr. Monaghan stated that the manufacturer strongly recommends that this drug be given at low quantities for a short period of time. He added that utilization of this drug is low.

MOTION: Keith Macdonald motioned to accept the criteria as presented.
SECOND: Dr. Parker
VOTES: Unanimous
MOTION CARRIED.

F. Fentanyl citrate (Actiq)

-Added: Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain.
-Criteria 1 added (recipient has been diagnosed with cancer)
-Remove Criteria 2 (diagnosis of pain unresponsive to other therapy).
-Continue with currently edit for a quantity limit of four units per day.

Mr. Monaghan stated that that there has been a significant abuse problem with this drug.

Mr. England expressed concern with limiting the drug to cancer pain only as there could be a rationale for use with non-cancer pain.

Mr. Monaghan agreed, however, stated that the cases he's reviewed and shared with the Nevada State Board of Pharmacy show that patients not controlled on their long-acting narcotic are getting escalating doses of Actiq. This is poor pain management and the consultants he's conferred with agree. For short-term therapy, it may be appropriate but there are many oral narcotic agents that are effective for short-term or breakthrough pain.

Dave England asked about use in children and Mr. Monaghan replied there has been very little utilization in children.

Dr. Parker asked what physician types are prescribing this and Mr. Monaghan replied primarily pain management physicians. He added that the reason for implementing the four units per day quantity limit is that some recipients were getting 12-14 per day.

Mr. England stated that if there is literature-supported rationale for use other than cancer pain, he would support those options for use, but is not in favor of more than four per day.

Mr. Monaghan reminded the Board that these warnings are from the manufacturer and not from the State or First Health.

Dr. Parker expressed concern in limiting use to cancer pain. If a pain specialist feels they need to prescribe Actiq, the patient is appropriate for getting the drug, and the physician can provide legitimate documentation to Medicaid, it should be considered. He suggested implementing a system monitoring physicians' prescribing patterns.

Keith Macdonald stated that he is one of the administrators of the Controlled Substance Task Force. Some doctors claim to be pain management specialists but have no certification and are generally the people who have the least reliable therapy for pain management.

Mr. England asked that when the PA is requested and there is legitimate value that can be documented in the literature, can approval be granted for non-cancer pain limiting use to four per day.

Mr. Monaghan stated yes but clear evidence-based criteria will need to be provided. He asked if the direction is to work with prescribers and gradually transition recipients currently on the drug.

Mr. England suggested patients be allowed to continue on the drug for up to 90 days and be reevaluated and converted, if necessary. He stated that he is not in favor of grandfathering.

Dr. Uhalde asked if there is a valid reason for the drug, can the denial be appealed. Mr. Monaghan stated that any denial can be appealed. Dr. Uhalde suggested keeping the rule restrictive and request justification be provided for the exceptions.

Public Comment

Richard Harris, M.D., stated that he is a pain management specialist, board certified anesthesiologist, hospice and palliative care physician, and is currently representing Cephalon Pharmaceutials.

He said that the restriction at the FDA level in regard to cancer pain was not the original application from Cephalon. The original application was for breakthrough pain in opioid-tolerant patients. Breakthrough pain requires a wide variety and access to numerous agents to manage and added that he did not defend the prescribing of twelve units per day. He felt that black box warnings typically fall into two categories from a clinical perspective:

1) warning to the physician in regard to the idiosyncractic, unknowable, unpredictable events that are serious in their consequence, and

2) restatement of the fundamental premise and clinical basis upon which this medication is going to be prescribed.

He agreed, from a clinical standpoint, that this is not the number one breakthrough agent.

Dave England stated that he agreed with Drs. Uhalde and Parker that there may be rationale for use for non-cancer, chronic breakthrough pain if sufficient documentation from the clinician as to the diagnosis, evaluation, treatment plan and documented failure of other medications is provided.

Dr. Parker asked what is the protocol for obtaining a drug outside of the approved indications?

Dave England replied that if the prescriber calls into FHSC and has documentation of failure, authorization will be granted.

Jeff Monaghan stated that if criterion 2 is eliminated, which has been proposed, and a physician calls in for authorization for non-cancer pain, the request will be denied. The denial can be appealed by the physician or patient. Ms. Lawrence added that the appeal process can take up to 21 days.

Darrell Faircloth stated that the discussion appears to intend that the drug be allowed with some restrictions and some documentation requirement for either criteria one or two and that the limit of 4 units per day be applicable to either use under one or two. He suggested a clear record of the intent be made before a motion is formulated.

Dr. Parker recommended that a one-month supply be approved for indications other than cancer pain. He suggested that the submission of a letter of justification from the physician be required within the 21-day appeal process stated by Ms. Lawrence. This would allow a month to review for appropriateness, the patient would not be without pain medication during that time and the physician would be aware that prescribing patterns are being monitored.

Ms. Lawrence stated that First Health, on behalf of the State, has 24 hours to respond to a prior authorization request through Point of Sale. This policy was created from this same board. She suggested consideration be given to have criteria 1 remain as written and add to criteria 2, "diagnosis and documentation of pain unresponsive to other therapy". Including this on the PA form would eliminate the wait for a letter to be sent for continuation of therapy. She also suggested reviewing utilization through the RetroDUR process profiling usage by patient or physician.

Dr. Parker stressed, and Mr. England agreed, that if approval is granted, the prescriber should be made aware that the prescribing of this product will be actively reviewed by the Medicaid Program.

MOTION: **Dr. Parker motioned that criteria 1 be accepted as presented; criteria 2 remain as written adding that the physician will be notified, if granted approval to use this medication for other than cancer pain, prescribing of this medication for non-cancer pain will be monitored by the Medicaid Program.**

SECOND: **No Second**

MOTION TABLED UNTIL THE NEXT MEETING

VI. Presentation by First Health Services and Discussion by Board of Prospective Drug Utilization Review (Pro DUR) Reports

A. Top 50 Drugs Ranked by Payment Amount

B. Top 10 Therapeutic Classes by Payment Amount
C. Pro DUR Message Report

Jeff Monaghan presented the ProDUR reports (attached). He stated that a year ago, the gross drug spend was escalating at 28% per year. This year, the rate is 5.3%. The amount paid per claim and the amount paid per utilizer has decreased. The increase has occurred in the number of utilizers and number of recipients as well as expensive drugs, particularly the antihemophilic factors. Two years ago, approximately $300,000 was spent on antihemophilic factors. This year the cost will be $6 million. In spite of those dynamics, the demonstrated ability to control costs and flatten the rate of increase is commendable.

Mr. Macdonald requested comparative charts of previous and current years as well as recipient load be presented at a future meeting.

Mr. Monaghan stated that he has prepared an executive summary and will distribute copies of that as well as the annual report (Agenda Item VII) to the Board. This item will be agendized for the next meeting.

VI. Presentation by First Health Services and Discussion by Board of Nevada Medicaid Drug Utilization Review Annual Report – Federal Fiscal Year 2004

Mr. Monaghan will distribute copies of the report to the Board.

VII. Presentation by First Health Services of Retrospective Drug Utilization Review Results

Jeff Monaghan presented the results (attached) of the RetroDUR for the period 12/04 through 03/05 for Committee review.

IX. Old Business

A. Update from First Health Services Regarding Implementation of Denials for Pro DUR Severity Level One Messages

Jeff Monaghan stated that at the 9/23/04, meeting, the DUR Board approved the implementation of prospective drug use review (ProDUR) denials for certain categories (drug-drug interaction, therapeutic duplication, etc.) In the past, pharmacies were not required to respond to ProDUR messages. Effective 6/17/05, hard denials were implemented requiring an intervention and outcome code at the pharmacy level. Since implementation, the therapeutic duplication (TD) and ingredient duplication (ID) denials have been turned off. It was determined, upon further review that the TD and ID denials were predominantly for drugs such as warfarin, duplicate narcotics, etc. He presented a draft notification to pharmacies which outlines modification of the edits and provides more code options.

Mr. England asked if notification was sent out prior to implementation and also wanted to ensure that the pharmacies were informed that this was a directive by the DUR Board for patient safety as well as the pharmacies'.

Mr. Monaghan stated yes to both questions.

X. Public Comment

No Comment.

XI. *Adjourn

Dave England asked if there was anything new to report regarding the process to allow pharmacists to initiate prior authorization (PA) requests.

Coleen Lawrence said that the State has not progressed any further on this issue and that research on what other state agencies are doing as well as what the regulations allow are needed.

Mr. England stated that he looks forward to a report at a future meeting.

Mr. Monaghan stated that the Board will be notified of the date, time and location of the next meeting.

MOTION: Dr. Parker motioned for adjournment.
SECOND: Keith Macdonald
Meeting adjourned at 2:58 p.m.